

Office Action Summary	Application No. 10/659,178	Applicant(s) MADGE ET AL.	
	Examiner YEVEGENY VALENROD	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22, 37, 38, 40-55, 57 and 59-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22, 37, 38, 40-55, 57, 59-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>1/6/10</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/24/08</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Rejection of claims 14-22, 37, 38, 40-55, 57 and 59-72 under 35 USC 103(a) over Rewinkel in view of Nanteuil and in further view of Adams is withdrawn. Applicants' amendments to the claims and remarks filed 11/9/09 have been found persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-22, 37, 38, 40-55, 57, 59-72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23, 25, 50-56 and 71-73 of U.S. Patent No. 7,112,572 ('572). Although the conflicting claims are not identical, they are not patentably distinct from each other

because the all the limitations of the instant claims are found in the cited claims of ('572).

Instant claims are directed to a pharmaceutically acceptable base addition salt of a boronic acid of formula (I) in claim 1, or formula (II) in claim 14, to formulation of the said salt in claims 26-28, pharmaceutical formulations in claims 50-56, anhydride comprising salts in claims 71-73.

Claim 2 of '572 claims a structure that encompasses the structure of the instant claim 1. Claim 12 of '572 displays a structure that is identical compound of formula (II) in the instant claim 14. Claims of '572 that directed to a salt and are dependent on claims 2 and 12 have all of the limitations of the instant claims 1-23 and 30-38. The formulations and medicament claimed in the instant claims 26-28 are obvious over claims 20, 23 and 25 of '572. The said formulation and medicament claims differ from the instant invention in that the compounds from which the formulation and medicament is made are not identical to the compound in '572. However, compound (III) of '572 encompasses all of the instantly claimed compounds, and compound (IV) of '572 is specie of the instantly claimed compound (I).

Claims 14-22, 37, 38, 40-55, 57, 59-72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 7,371,729 ('729). Although the conflicting claims are not identical, they

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are not patentably distinct from each other because the all the limitations of the instant claims are found in the cited claims of ('729).

Instant claims are directed to a pharmaceutically acceptable base addition salt of a boronic acid of formula (I) in claim 1, or formula (II) in claim 14, to formulation of the said salt in claims 26-28, pharmaceutical formulations in claims 50-56, anhydride comprising salts in claims 71-73.

Claim 1 of '729 claims a pharmaceutical formulation comprising boronic acid salt of the instant claims. The difference is in that the instant claim 14 is directed to a pharmaceutically acceptable salt, while claim 1 of '729 is directed to a pharmaceutical composition. The pharmaceutical composition comprising the instantly claimed boronic acid salt inherently comprises the pharmaceutically acceptable salt of the instant invention.

Conclusion

Claims 14-22, 37, 38, 40-55, 57, 59-72 are pending.

Claims 14-22, 37, 38, 40-55, 57, 59-72 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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